UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,594	08/19/2003	Tony N. Frudakis	DNA1170-2	6207

28213 7590 05/12/2008

DLA PIPER US LLP
4365 EXECUTIVE DRIVE
SUITE 1100
SAN DIEGO, CA 92121-2133

EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,594	FRUDAKIS ET AL.	
	Examiner	Art Unit	
	PABLO WHALEY	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 83-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 83-115* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims Under Examination

Claims 1 and 83-115 are under examination. Claims 2-82 are cancelled.

Priority

This application has been granted the benefit of priority to US Provisional Application 60/404,357, filed 8/19/2002.

Withdrawn Rejections

The rejection of Claims 1 and 83-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of applicant's amendments filed 01/11/2008 to claim 1 which now recites "test" individuals.

The rejection of claims 1 and 83-115 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's arguments and amendments filed 01/11/2008.

The rejection of claims 1, 84-86, 90, 92-97, 100, 104, and 105 under 35 U.S.C. 103(a) as being unpatentable over Parra et al, in view of Ott et al., in view of Halushka et al. is withdrawn in view of applicant's arguments and Declaration under 37 CFR 1.132 signed by Tony Frudakis (applicant), both filed 01/11/2008, that the combination of references does not teach the use of SNPs that are not located within a gene encoding region.

The rejection of claims 87-89, and 110-115 under 35 U.S.C. 103(a) as being unpatentable over Parra et al., in view of Ott et al. and Halushka et al., and further in view of Sorenson et al. is withdrawn in view of applicant's arguments and Declaration under 37 CFR 1.132 signed by Tony Frudakis (applicant), both filed 01/11/2008, that the combination of references does not teach the use of SNPs that are not located within a gene encoding region.

The rejection of claims 97-99, 101-103, and 106-109, are rejected under 35 U.S.C. 103(a)

as being unpatentable over Parra et al., in view of Ott et al. and Halushka et al., and further in view of Kanetsky et al., Pritchard et al., and Pritchard et al. is withdrawn in view of applicant's arguments and Declaration under 37 CFR 1.132 signed by Tony Frudakis (applicant), both filed 01/11/2008, that the combination of references does not teach the use of SNPs that are not located within a gene encoding region.

The rejection of claims 1, 83-91, 95-99, and 107-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shriver et al. (Am. J. Hum. Genet., 1997, Vol. 60, p.957-964), in view of Daly et al. (Nature Genetics, 2001, Vol. 29, p.229-232) and Kruglyak (Nature Genetics, 1997, Vol. 17, p.21-24) is withdrawn in view of applicant's arguments and Declaration under 37 CFR 1.132 signed by Tony Frudakis (applicant), both filed 01/11/2008, that the combination of references does not teach the use of SNPs that are not located within a gene encoding region.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 83-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "gene encoding region." It is unclear as to the metes and bounds of said "gene encoding region" because it is not clear if the claimed subject matter excludes SNPs that are within a promoter region or an intron. *This rejection is newly applied.*

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 83-115 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons. *This rejection is newly applied.*

Claims 1 and 83-115 are drawn to a method of inferring proportional ancestry of at least two ancestral groups. For a process to be statutory, it must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)]. As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result. The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to a process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility.

In the instant case, the claimed method does recite a physical transformation of matter (i.e. contacting samples with a SNPs). However, the claimed invention as a whole results in "identifying" a population structure. This is not a tangible result because "identifying" a

population structure does not communicate a result in a user readable format. The revised Guidelines also state that the focus is "not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the final result achieved by the claimed invention is useful, tangible, and concrete." Therefore the claimed method does not recite a practical application of a 35 U.S.C. 101 Judicial exception and is not statutory.

This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, in a graphical format or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 83-86, 90-101, and 104-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parra et al. (Am. J. Physical Antropol., January 2001, Vol. 114, Issue 1, p. 18-29), in view of Shriver et al. (American Journal of Human Genetics, 1997, Vol. 60, p.957-964) in the IDS filed 5/20/2004, in view of Kaessmann et al. (Nature Genetics, May 1999, Vol. 22, p.78-81), and in view of Vines (New Scientist, 1995, Vol. 147, No. 1985, p.34-42). *This rejection is newly applied.*

Parra teaches a method for inferring ancestral proportions and admixture in six different populations from different regions [See Abstract]. Parent populations and non-parental populations are disclosed [p.19, Subjects and Methods]. Parra identifies a population of ten SNP markers comprising and delta values > 0.4 between one or more populations [Table 1, last column]. Parent samples are contacted with markers using standard PCR genotyping for determining allele frequencies [See p.20, Col. 1 and Table 1, last column]. A combination of SNP markers are selected to obtain an estimate of admixture for a sub-population [p.21, Col. 1, ¶ 2, and Fig. 1], wherein allele frequencies of the SNP markers are > 1% [Table 1], which is a teaching for minor allele frequencies. Parra shows the use of markers that are unlinked to certain loci [p.20, Col. 1, and p.23, Col. 2]. Parra calculates the frequency differences between populations based on SNPs [p.23, Col. 2]. The population structure is then determined using a predetermined confidence interval and infers the proportional ancestry of the non-parental population [p. 21 and Table 2]. Parra also shows fitting genotype frequencies to Hardy-Weinberg proportions and suggest the selection of genetic markers that show homogeneity with Africa and Europe based on allele frequency [p.20, Statistical Analysis]. Additionally, Parra shows two-way and three-way comparison of populations that are both intracontinental and intercontinental

[Table 1, Fig. 1, and p. 22], with delta values > 0.4. Parra discloses a biogeographical ancestry trait (BGA) [Fig. 1], and admixture proportions of samples estimated using maximum likelihood calculations [p.20, Col. 2, ¶2 and ¶3]. Parra shows proportional ancestry comprising a three-way comparison of sub-populations of African-Americans and the distribution percentage of European alleles within this sub-population [Fig. 1] derived from maximum-likelihood methods [p.25, Col. 2]. Parra shows SNPs detected in a subpopulation of non-parental individuals for determining sub-population structure [Fig. 1].

Parra does not specifically teach selecting SNPs to generate a second population of SNPs that are not located within a gene encoding region, as in claim 1 (step c).

Parra also does not specifically teach performing a likelihood determination for affiliation with an East Asian ancestral group as required by claims 98, or four-way comparisons as in claim 101.

Shriver teaches a method for identifying a set of genetic markers using likelihood analysis that allows the confident determination of ethnicity for use in a forensic setting [Abstract and p.964, Discussion]. In particular, Shriver presents population specific alleles (PSAs) [p.957, Col. 2], as well as methods for calculating allele-frequency differentials between test samples of different populations [p.958, Col. 2] and for calculating likelihood values for different loci [Table 1, and Table 2]. Shriver does not specifically teach "four-way" comparison. However, Shriver performs two-way and three-way comparisons between multiple populations [Fig. 1-4]. Therefore, it would be obvious to one of ordinary skill in the art to perform a four-way comparison among four ancestral groups, as in claim 101. Shriver also suggests similar markers could be developed for the identification of other populations including those of Asian origin [p.963, last ¶, Col. 1].

Kaessmann teaches the use of non-coding region DNA for purposes of determining point mutations (i.e. SNPs) and gaining insight to human ancestry [p.78, Col. 1 and 2]. A class of nuclear loci that is useful for evolutionary analysis is also disclosed [p.80, Col. 2]. Kaessmann also shows a map of the world indicating approximate origins of individuals studied [Fig. 1]. Kaessman also shows that the use of non-coding DNA in inheritance applications is advantageous because it is highly unlikely to be the direct target of positive or negative selection [p.79, Col. 1].

Vines shows the benefit of using "neutral" loci and junk DNA for determining ancestry in genomic ancestry applications and forensic science applications [p.36, Body of Evidence, Col. 1, 2, and 3].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Parra to select a second set of SNPs from non-coding region mutations as taught by Shriver and Kaessmann, since DNA markers offer little power to distinguish ethnicity of an individual, as suggested by Shriver [Abstract]. One of ordinary skill in the art would have been motivated to combine the above teachings in order to improve ancestral prediction by using markers from non-coding DNA regions that are highly unlikely to be the direct target of positive or negative selection , as suggested by Kaessmann [p.79, Col. 1] with predictable results, as suggested by Vines [p.36, Body of Evidence, Col. 1, 2, and 3].

Claims 87-89 and 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parra et al. (Am. J. Physical Antropol., January 2001, Vol. 114, Issue 1, p. 18-29), in view of Shriver et al. (American Journal of Human Genetics, 1997, Vol. 60, p.957-964), in view of Kaessmann et al. (Nature Genetics, May 1999, Vol. 22, p.78-81), and in view of Vines (New Scientist, 1995, Vol. 147, No. 1985, p.34-42), as applied to claims 1, 83-86, 90-101, and 104-109 above, and further in view of Sorenson et al. (US 2003/0172065; Filed Mar. 29, 2002). *This rejection is newly applied.*

Parra, Shriver, Kaessmann, and Vines make obvious a method for inferring ancestral proportions and admixture, as set forth above.

Parra, Shriver, Kaessmann, and Vines do not specifically teach contacting samples with high numbers of SNPs as in claims 87- 89. Parra, Shriver, Kaessmann, and Vines do not specifically teach proportional ancestries comprising a photo of a person from whom the known proportional ancestry was determined, as in claims 110-115.

Sorenson discloses a genealogical research and record keeping system for identifying commonalities in haplotypes from biological samples [Abstract]. In particular, Sorenson teaches thousands of known genetic markers and millions of characterized SNPs may be analyzed [0042], [Fig. 4] for identifying a population structure [0032], [0046]-[0047] that correlates with markers and a trait, as in claim 87-89. Sorenson also discloses prior art genetic records of human eye, hair and skin color, height and other physical characteristics [0009], and ancestral data stored on microfiche and on a number of other electronic media formats including the internet [0003], which is broadly interpreted as a teaching for digital information and pictures as in claims 110-115.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method made obvious by Parra, Shriver, Kaessmann, and Vines using high numbers of SNPs and image data as taught by Sorenson et al., in order to identify previously unknown biological relationships by automatically correlating genetic information with genealogical information [Sorenson, 0015], resulting in the practice of the instantly claimed invention with predictable results.

Claims 102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parra et al. (Am. J. Physical Antropol., January 2001, Vol. 114, Issue 1, p. 18-29), in view of Shriver et al. (American Journal of Human Genetics, 1997, Vol. 60, p.957-964), in view of Kaessmann et al. (Nature Genetics, May 1999, Vol. 22, p.78-81), and in view of Vines (New Scientist, 1995, Vol. 147, No. 1985, p.34-42), as applied to claims 1, 83-86, 90-101, and 104-109 above, and in further view of Pritchard et al. (Theoretical Population Biology, 2001, Vol. 60, p. 227-237). *This rejection is newly applied.*

Parra, Shriver, Kaessmann, and Vines make obvious a method for inferring ancestral proportions and admixture, as set forth above.

Parra, Shriver, Kaessmann, and Vines do not specifically teach generating a graphical representation, as in claims 102 and 103.

Pritchard teaches methods for inferring proportional ancestry of different ancestral groups, and graphically displaying ancestral results in triangular format [Fig. 1], as in claims 102 and 103. Pritchard also teaches a computer-based program STRUCTURE for estimating population structure for 20 data sets of 50, 200, and 1000 biallelic markers [p. 232, Results].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to practice the method made obvious by Parra, Shriver, Kaessmann, and Vines with an additional step for generating ancestral maps and displaying results in triangular format, as taught by Pritchard, since both Parra and Shriver present their results in graphical format, as set forth above, and since Pritchard also estimates population structure. One of ordinary skill in the art would have been motivated to combine the above references in order to use a user-friendly graphical method for inferring ancestry in a plurality of populations, as suggested by Pritchard [Fig. 1].

Response to Arguments

Applicant's arguments and Declaration under 37 CFR 1.132 signed by Tony Frudakis (applicant), both filed 01/11/2008, that the cited combination of references do not teach the use of SNPs at neutral loci that are superior for determining ancestry have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground of rejections are made in view of applicant's arguments and Declaration, filed 01/11/2008, as summarized above. Is it noted that applicant's arguments that the cited prior art does not teach SNPs at "neutral loci" are not persuasive since the claims do not recite "neutral loci." This limitation is interpreted as SNPs in non-encoding regions. It is also noted that the specification does not provide a limiting definition for "gene encoding region." Therefore a SNP that is not within a gene encoding region reasonably includes promoters, 3' regions, and introns. Additionally, the Declaration, filed 01/11/2008, argues that the instant claims are distinct because they are directed to a method of genomic ancestry, and that the cited prior art is directed to methods of "confounded" ancestry. However, these arguments are not persuasive as the instant claims require "proportional" ancestry and do not recite limitations directed to "genomic" ancestry.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Pablo S. Whaley/

Patent Examiner

Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631